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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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18M2/0107

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EXAMINER	
AL[illegible]	

ART UNIT	PAPER NUMBER
818	

01/07/97

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/607,485	Lee et al.
Examiner	**Group Art Unit**
Marianne P. Allen	1818

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *4-10, 17, and 18* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *4-10, 17, and 18* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Serial Number: 08/607,485

Art Unit: 1818

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1818.

Claims 1-3, 11-16, and 19-21 have been cancelled.

Claims 4-10 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 4-10 are drawn to mammalian GDF-1 protein, or an epitope specific thereto, or functionally equivalent variations thereof. The specification fails to enable how to use the GDF-1 protein in the manner set forth in the specification. Biological properties are alleged based upon the similarity of the GDF-1 amino acid sequence to the TGF-β family. However, there is no evidence of record that GDF-1 is a biologically useful protein possessing any particular properties. (See specification pages 10-11.) The similarities between GDF-1 and the TGF-β family members range from 26-52% on the amino acid level and these proteins are not deemed to be predictive of the biological properties possessed by GDF-1. The biological activities of the TGF-β family are diverse and it could not be predicted which activity GDF-1 would have, if any. As such, the specification does not enable using the GDF-1 protein as disclosed in the specification. For

example, there is no evidence of any disease state that can be treated with this protein nor any tumors, genetic diseases, or developmental anomalies that applicant has associated with this gene or protein.

Claims 17-18 are drawn to mammalian UOG-1 protein, or an epitope specific thereto, or functionally equivalent variations thereof. The specification does not tell how to use UOG-1 protein, specific epitopes, or functional variations. The specification speculates that the full length protein may be a receptor and may be involved with the biological activity for GDF-1. (See page 15, lines 9-29.) As the GDF-1 protein activity has not been established as set forth above and the structural features upon which identity as a possible receptor are based are ill-defined, there is reason to doubt this statement. Many membrane spanning proteins exist that are not receptors and many proteins have hydrophobic regions. No further disclosure is provided to guide one of ordinary skill in the art to the use of the protein.

The specification does not disclose how to define unique or specific epitopes of GDF-1 or UOG-1.

The specification does not define the metes and bounds of functionally equivalent variations. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe nor enable identification of any other proteins meeting the functional limitations of the claims and it is deemed to constitute undue experimentation to determine them. The enablement of the claims can be viewed similarly to those in Ex parte Maizel, 27 USPQ2d 1662, 1665. The Board of Patent Appeals and

Interferences held that claims drawn to DNA sequences encoding biologically equivalent proteins (i.e. DNA encoding proteins that do not have a defined amino acid sequence) are not enabled when the specification discloses a single specific DNA sequence known to the inventor having the biological limitations. The disclosure was held not to be commensurate in scope with the breadth of such claims because DNA sequences encoding biologically equivalent proteins covers any DNA sequence encoding a protein which achieves the stated biological result. Here the claims are not directed to DNA sequences encoding proteins but rather are directed to the biologically equivalent proteins themselves. The specification does not characterize the UOG-1 or GDF-1 proteins with respect to their biological activity or the amino acids required to maintain this activity. Thus, it would constitute undue experimentation to determine functional equivalents in the absence of further guidance. The disclosure is not commensurate in scope with the breadth of the claims.

Claims 8-9 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claims 8-9 refer to GDF-1 and the preamble of claim 18 refers to UOG-1. However, the body of all three claims refers to the amino acid sequence of Figures 11A or 11B. The body of the claims do not specifically refer to the GDF-1 amino acid sequence (claims 8-9) or the UOG-1 amino acid sequence (claim 18) and both are present in the Figures.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 4-10 are rejected under 35 U.S.C. § 102(e) as being anticipated by Derynck et al. (U.S. Patent No. 4,886,747).

Derynck et al. teaches the amino acid and nucleotide sequences for mammalian TGFβ1, TGFβ2, and TGFβ3. Vectors and transformed host cells are disclosed as well as a method of making the proteins recombinantly. (See abstract, claims, figures 1-5, Example 5.) It is noted that the TGFβ1, TGFβ2, and TGFβ3 sequences have amino acids in common with the GDF-1 sequence of Figure 2 in the specification.

The specification defines GDF-1 to include any "unique portion" which is poorly defined in the specification. (See page 7.) It is unknown if the five or six amino acids or 15 or 18 nucleotides must be contiguous, as in a sequence, or must merely be present in the sequence. In addition, the specification does not define the metes and bounds of "functionally equivalent variation." As GDF-1 is stated to be part of the TGFβ superfamily, Derynck et al. is deemed to be an anticipatory reference for the invention as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The most convenient FAX telephone number for this examiner is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.